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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,352	02/27/2006	Albert Schomig	17601.55A.1.1	5048

57360 7590 09/14/2010

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EXAMINER
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GANESAN, SUBA

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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09/14/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/528,352	SCHOMIG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SUBA GANESAN	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,21-28 and 31-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,21-28 and 31-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1, 3-6, 21-28, 31-42 have been considered but are not persuasive. Applicant argues that Yan and Callol do not teach or suggest that it would be beneficial or desirable to have a stent with a roughened external surface having sandblasted particles. This is not persuasive; Yan and Callol recognize the benefits of a roughened surface on a stent and Callol teaches sandblasting as a suitable means of achieving a roughened surface. Because Callol teaches the same process as Applicant's claimed process, the resultant product is expected to be the same.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims **22-24** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The term "devoid of imperfections" in claim 22 is a relative term which renders the claim indefinite. The term "imperfections" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction is requested.

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5. Claims 23-24 are indefinite; Claim 23 recites "roughened surfaces are a uniform surfaces with increased flow dynamics and less turbulence". This is unclear grammatically and confusing, as roughened surfaces have surface irregularities.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims **1, 3, 5-6, 21-28, 34-35, 37-40, and 42** are rejected under 35

U.S.C. 103(a) as being obvious over Yan (U.S. Pat. No.: 5,843,172) in view of Callol et al. (U.S. Pat. No.: 6,174,329), with supporting evidence from Wu et al. (6,805,898).

7. Yan teaches a stent system for placement in a body lumen which is expandable from a contracted state to an expanded state (col. 1 lines 5-10), comprising: a stent having a roughened exterior surface (fig. 1 and 2), wherein at least a portion of the exterior surface is roughened to a predetermined extent for coating (see fig. 2). The entire stent wire is porous, therefore it is expected that the inner and side surface of the stent are roughened to a predetermined extent (col. 4 lines 23-27). Yan further teaches a polymer-free external coating consisting of a therapeutic agent disposed directly on the exterior of the stent (col. 2 lines 15-38). The stent is stainless steel (col. 4 line 33). The stent is balloon expandable (col. 8 lines 1-2). The stent can be annealed (col. 4 lines 37-39).

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8. However, Yan lacks a stent that is sandblasted to create surface roughness and thus also lacks surface particles that have been subjected to sandblasting. Sandblasting with sand, glass beads, or corundum is considered a product-by-process limitation that is not given patentable weight in the absence of distinguishing structure (See MPEP 2113). Because both the Yan stent and a sandblasted stent result in the structure of a rough-surface stent, the specific process claimed to achieve Applicant's rough surface is not required to meet the claim.

9. Alternatively, Callol teaches the use of sandblasting as a suitable means for roughening a stent surface (col. 7 lines 23-27) in order to improve adhesion between layers. Therefore, if a sandblasted surface is not equivalent to the surface of Yan, it would have been obvious to utilize sandblasting as the means to roughen the stent surface for the purpose of improving adhesion between the stent surface and the therapeutic agent. The use of sand, glass, or corundum would have yielded equivalent sand-blasted surfaces (Wu, U.S. Pat. No.: 6805898 teaches the roughening of surfaces using stand blasting and bead blasting are techniques that are well known in the art, col. 9 lines 25-38); consequently these specific materials are considered obvious equivalent choices to creating a roughened surface on a stent. Callol teaches coating the inner and outer surfaces of a stent (see fig. 6). Employing sandblasting techniques as taught by Callol with the stent of Yan would result in highly predictable results and would require no undue experimentation. Use of sandblasting is taught by Callol; it is expected that this method results in standblasted particles of sand, glass or corundum.

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2. Claims **4, 31-33, 36, 41** are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (U.S. Pat. No.: 5,843,172) in view of Callol et al. (U.S. Pat. No.: 6174329) as applied above, further in view of Sirhan (Pub. No.: US 2002/0082679).

3. Yan is explained supra. Yan further teaches the use of the drug stent to treat restenosis (col. 1 lines 12-30). However, Yan lacks specific disclosure of the drug Tacrolimus. Sirhan is also concerned with restenosis (see abstract) and teaches the use of tacrolimus as a suitable drug for therapeutic treatment (para. 30). Selecting a known material based on its suitability for an intended use is considered within the level of ordinary skill of a worker in the art (see MPEP 2144.07). Therefore, it would have been obvious at the time the invention was made to have provided the stent of Yan with the specific drug Tacrolimus, as taught by Sirhan, for the purpose of treating restenosis with a suitable therapeutic agent.

### ***Conclusion***

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./  
Examiner, Art Unit 3774

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738